DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION, Federal Y2K Biomedical Equipment Clearinghouse
Product Problem - FORM FDA 3469A

Form approved: OMB No. 0910-0417
Expiration Date: May 31, 2000
See OMB Statement on reverse

Please verify and correct, or provide any missing information and return as indicated on the instruction page.
For detailed instructions, please refer to the appropriate line number on the **BACK** of this form.

Line #		
	Manufacturer Information	
1.	Manufacturer Name	
2.	Division *(see instructions on the back of this form)*	
3.	Enter Your FDA Assigned Owner/Operator Number	
	Product Problem Information	
4.	Is this product FDA regulated?	❑ **YES** ❑ **NO**
5a.	You previously reported the type of product as:	
5b.	To clearly identify the type of product please provide the FDA Classification Number *(see instructions on the back of this form)* Generic Description *(e.g., mass spectrometer) Only for non-FDA-classified or scientific research equipment.*	8 ☐☐.☐☐☐☐ **FOR DETAILS AND INSTRUCTIONS SEE THE ENCLOSED LIST OF PRODUCT CLASSIFICATION NAMES.** *(For a product that has not been classified by the FDA or is scientific research equipment, please provide a generic description in the block below.)*
6.	Trade or Brand Name	
7.	Model Number(s)	
8.	Original Manufacturer *(Name of the manufacturer under which this product was originally marketed.)*	
9.	Serial Number(s)	
10.	Software Version Number(s)	
11.	Date-Related Problem *1. What specifically will happen?* *2. How will the date-related problem affect the device's functioning as it relates to its intended use? Please describe.* *3. Does the transition from Dec 31, 1999, to Jan. 1, 2000, or between two other times, introduce unexpected or incorrect performance or functioning of the product? Please describe.* *(If necessary, please use an additional sheet of paper.)*	
12.	Solution *(Please check (✓) only ONE box)*	Software Upgrade No Cost Software Upgrade at a Cost Hardware Upgrade No Cost Hardware Upgrade at a Cost Minor Problem, No Upgrade Obsolete, No Upgrade Assessment In Progress
13.	Solution Date *(Not required for products reported to have Minor Problems or for products which are Obsolete.)*	**(mm/dd/yyyy)**
14.	User Action Necessary *(If applicable, describe any other action the user must take in order for the product to function as designed and expected.)* *(If necessary, please use an additional sheet of paper.)*	*Does the product require operator intervention, reinitializing, or manual date setting to function correctly after a given date? Please describe.*

INFORMATION CURRENT AS OF 2/24/2000 DUPLICATE THIS FORM AS NECESSARY
COMPLETE ONE FORM FOR EACH PRODUCT WITH A DATE-RELATED PROBLEM

Federal Y2K Biomedical Equipment Clearinghouse
Instructions – FORM FDA 3469A

This form has been filled-in with the information your company has provided, if applicable. Please verify and correct, or provide any missing information and return as indicated on the instruction page.

If you have questions about completing this form or the Federal Y2K Biomedical Equipment Clearinghouse please call 1-877-744-1522 between 8:30am and 5:00pm Monday through Friday, Eastern Time or Email the Y2K Clearinghouse at y2kstatus@bah.com. You may also fax your completed forms to 1-301-881-1848.

Line Number Key

Manufacturer Information	
1. Manufacturer Name	Name of the Manufacturer submitting the product information.
2. Division	Name of the Division, if this report is for ONE specific division. Complete ONE form for each division that manufactures biomedical equipment. Please leave blank if you are reporting for the entire company.
3. Enter Your FDA Assigned Owner/Operator Number	If the Manufacturer submitting Y2K compliance information is FDA regulated, please enter your FDA assigned Owner/Operator Number.
Product Problem Information	
4. Is this product FDA regulated?	Is this product FDA regulated?
5a. Previously Reported Product Type	Name of the product type previously reported to the Y2K Clearinghouse. If reporting a new product, this field should be left blank.
5b. FDA Classification Number	Use the device classification as identified in the Device Classification Regulation of 21 CFR 860-892 (enclosed). For a product that has not been classified by the FDA or is scientific research equipment, please provide a generic description in the block provided (e.g., mass spectrometer).
6. Trade or Brand Name	Commonly used name that identifies the product (i.e., the name that appears on the product label).
7. Model Number(s)	Model number or range of numbers associated with the product that uniquely identifies it.
8. Original Manufacturer	Identify the name of the manufacturer under which this product was originally marketed, if it is different than Line #1.
9. Serial Number(s)	Serial number or range of numbers for products with the problem described, if applicable.
10. Software Version Number(s)	Software version or range of numbers for products with the problem described, if applicable.
11. Date-Related Problem	Detailed description of the Y2K date-related problem.
12. Solution	Solution to be offered by the manufacturer. Check ( ) only ONE that applies to the product. Software upgrade will be provided at no cost to the purchaser. Software upgrade will be provided at a cost to the purchaser. Hardware upgrade will be provided at no cost to the purchaser. Hardware upgrade will be provided at a cost to the purchaser. Minor Problem which will not affect the operation of the product – No upgrade will be provided. Product is Obsolete - No upgrade will be provided. Assessment In Progress.
13. Solution Date	Date that the solution will be available from the Manufacturer. A date is NOT required for products reported to have Minor Problems or products which are Obsolete.
14. User Action Required	If applicable, describe any other action the user must take in order for the product(s) to function as designed and expected.
COMPLETE ONE FORM FOR EACH PRODUCT WITH A DATE-RELATED PROBLEM	

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, search existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Year 2000 Coordinator (HFZ-Y2K)
Center for Devices and Radiological Health, FDA
9200 Corporate Boulevard
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

YEAR 2000 READINESS DISCLOSURE

Instructions – FORM FDA 3469A (2/2000)